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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/540,601	06/23/2005	Benito Munoz	MS0018YP	4252
210	7590	12/11/2006	EXAMINER	
MERCK AND CO., INC P O BOX 2000 RAHWAY, NJ 07065-0907			NOLAN, JASON MICHAEL	
			ART UNIT	PAPER NUMBER
			1626	

DATE MAILED: 12/11/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

10/540,601

Applicant(s)

MUNOZ ET AL.

Examiner

Jason M. Nolan, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 23 June 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-5, 8, 11, 14, 16-23 and 29-32 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☒ Claim(s) 1-5, 8, 11, 14, 16-23 and 29-32 are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____
- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

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DETAILED ACTION

Claims 1-5, 8, 11, 14, 16-23 & 29-32 are currently pending in the instant application.

Priority

This application is a 371 of PCT/US06/00424, filed on January 9, 2004.

Acknowledgement is made of Applicants' claim for benefit of US Provisional Patent Application 60/439,965 and 60/439,847, filed on January 14, 2003. Said claim has been made in the ADS and/or in the first paragraph of the Specification.

Specification

Applicant is reminded of the proper language and format for an abstract of the disclosure.

The abstract should be in narrative form and generally limited to a single paragraph on a separate sheet within the range of 50 to 150 words. It is important that the abstract not exceed 150 words in length since the space provided for the abstract on the computer tape used by the printer is limited. The form and legal phraseology often used in patent claims, such as "means" and "said," should be avoided. The abstract should describe the disclosure sufficiently to assist readers in deciding whether there is a need for consulting the full patent text for details.

The language should be clear and concise and should not repeat information given in the title. It should avoid using phrases which can be implied, such as, "The disclosure concerns," "The disclosure defined by this invention," "The disclosure describes," etc.

The abstract of the disclosure is objected to because legal phraseology is used.

Correction is required. See MPEP § 608.01(b).

Election/Restrictions

Restriction is required under 35 U.S.C. § 121 and § 372.

Claims 1-5, 8, 11, 14, 16-23 & 29-32 are drawn to more than one inventive concept (as defined by PCT Rule 13), and accordingly, a restriction is required according to the provision of PCT Rule 13.2.

PCT Rule 13.2 states that the international application shall relate to one invention only or to a group of inventions so linked as to form a single general inventive concept (requirement of unity of invention).

PCT Rule 13.2 states unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features.

Annex B, Part 1 (b), provides that "special technical features" mean those technical features, which, as a whole, define a contribution over the prior art.

Annex B, Part 1 (e), provides combinations of different categories of claims and states:

"The method for determining unity of invention under Rule 13 shall be construed as permitting, in particular, the inclusion of any one of the following combinations of claims of different categories in the same international application:

- (i) in addition to an independent claim for a given product, an independent claims for a process specially adapted for the manufacture of the said product, and an independent claim for use of the said product, or
- (ii) in addition to an independent claim for a given process, an independent claim for an apparatus or means specially designed for carrying out the said process, or
- (iii) in addition to an independent claim for a given product, and independent claim for a process specially adapted for the manufacture of the said product, and an independent claim for an apparatus or means specially designed for carrying out the said process,..."

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This application contains the following inventions or groups of inventions that are not so linked as to form a single general inventive concept under PCT Rule 13.1.

Due to numerous and widely divergent variables in the substituents of Formula (1), for example: R^1 , R^2 , X & A , a precise listing of inventive groups cannot be made.

The following groups are *exemplary*:

- Group I:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (1).
- Group II:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (2).
- Group III:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (3).
- Group IV:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (4).
- Group V:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (5).
- Group VI:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (6).
- Group VII:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (7).
- Group VIII:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (8).

- Group IX:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (9).
- Group X:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (10).
- Group XI:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (11).
- Group XII:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (12).
- Group XIII:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (13).
- Group XIV:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (14).
- Group XV:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (15).
- Group XVI:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (16).
- Group XVII:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (17).
- Group XVIII:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (18).
- Group XIX:** Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (19).

Group XX: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (20).

Group XXI: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (21).

Group XXII: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (22).

Group XXIII: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (23).

Group XXIV: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (24).

Group XXV: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (25).

Group XXVI: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (26).

Group XXVII: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (27).

Group XXVIII: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (28).

Group XXIX: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (29).

Group XXX: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (30).

Group XXXI: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (31).

Group XXXII: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (32).

Group XXXIII: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (33).

Group XXXIV: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (34).

Group XXXV: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (35).

Group XXXVI: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (36).

Group XXXVII: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (37).

Group XXXVIII: Claims 1-5, 8, 11, 14, 16-19, 22, 23, 29 & 30, drawn to compounds and compositions of Formula (1) wherein A is (38).

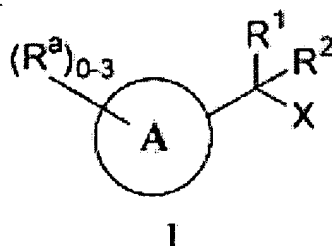
Group XXXIX: Claims 20, 21, 31 & 32, drawn to methods of using the compounds of Formula (I).

The claims herein lack unity of invention under PCT Rules 13.1 and 13.2 because, pursuant to 37 C.F.R. § 1.475(a) **Group I - Group XXXIX** lack unity of invention since, under 37 CFR § 1.475:

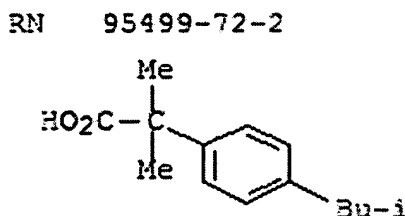
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Where a group of inventions is claimed in an application, the requirement of unity of invention shall be fulfilled only when there is a technical feature among those inventions involving one or more of the same or corresponding special technical features...those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

The structural moiety common to **Group I – Group XXXIX** is:



This technical feature is not a special technical feature, because it fails to define a contribution over the prior art (Smeyers *et al. Journal of Pharmaceutical Sciences* **1985**, 74(1), 47-9, compound RN 95499-72-2, wherein **R¹** and **R²** are methyl; **X** is CO₂H; and **A** is **(4)**):



Therefore, **Claims 1-5, 8, 11, 14, 16-23 & 29-32** are not so linked as to form a single general inventive concept and there is a lack of unity of invention. The variables vary extensively and when taken as a whole result in vastly different compounds. Additionally, the vastness of the claimed subject matter and the complications in

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understanding the claimed subject matter impose a serious burden on the search and examination of the claimed subject matter.

Therefore, since the claims do not relate to a single general inventive concept under PCT Rule 13.1 and lack the same or corresponding special technical features, the claims lack unity of invention and should be limited to a product or a method of use.

Furthermore, with respect to **Group I – Group XXXIX**, even if unity of invention under 37 CFR 1.475(a) is not lacking, under 37 CFR 1.475(b) a national stage application containing claims to different categories of invention will be considered to have unity of invention if the claims are drawn only to one of the following combinations:

- (1) A product and a process specially adapted for the manufacture of said product; or
- (2) A product and process of use of said product; or
- (3) A product, a process specially adapted for the manufacture of the said product, and a use of the said product; or
- (4) A process and an apparatus or means specially designed for carrying out the said process; or
- (5) A product, a process specially adapted for the manufacture of the said product, and an apparatus or means specially designed for carrying out the said process.

Moreover, according to 37 CFR 1.475(c),

If an application contains claims to more or less than one of the combinations of categories of invention set forth in paragraph (b), unity of invention might not be present.

In the instant case the claims are drawn to more than a product and a method of use, and according to 37 CFR 1.475(e),

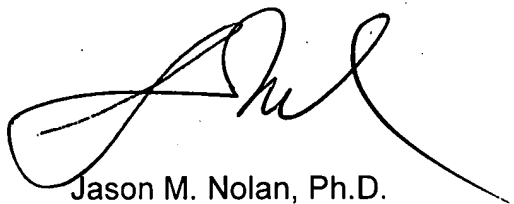
The determination whether a group of inventions is so linked as to form a single general inventive concept shall be made without regard to whether the inventions are claimed in separate claims or as alternatives within a single claim.

As a result, the claims lack unity of invention and applicant is required to elect a single invention.

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Telephone Inquiry

Any inquiry concerning this communication or earlier communications from the examiner should be directed to **Jason M. Nolan, Ph.D.** whose telephone number is **(571) 272-4356** and electronic mail is **Jason.Nolan@uspto.gov**. The examiner can normally be reached on Mon - Fri (9:00 - 5:30PM). If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, **Joseph M^cKane** can be reached on **(571) 272-0699**. The fax phone number for the organization where this application or proceeding is assigned is **571-273-8300**. Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Jason M. Nolan, Ph.D.
Examiner
Art Unit 1626



Joseph K. M^cKane
Supervisory Patent Examiner
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Date: December 4, 2006